

Serial No. 09/726,841Docket No. 30697Remarks:

Claims 7-10 and 16 remain for consideration in this application with claims 7 and 16 being in independent format. In view of the claims as they now stand, together with remarks hereunder, the rejections of the Office Action of March 12, 2003 must be traversed.

The present invention provides an improved feeding tube which allows an installer to quickly ascertain whether the tube is properly placed within a patient's esophagus. Generally speaking, the tube comprises an elongated tube presenting a distal end adapted for insertion into a patient and a proximal portion designed to remain outside the patient, a fixture operably coupled with the proximal portion, and one or more intermediate coupling members attached to the fixture. The coupling members are adapted such that they permit the attachment of a CO₂ detecting machine to the tube, and thereby the presence of CO₂ adjacent the distal end of the tube may be detected when the tube is inserted into a patient. Using the present invention reduces the potential of causing damage by unintentionally passing the feeding tube into the respiratory tract.

Claims 7-10 were rejected under 35 U.S.C. 103(a) as being obvious over Piontek in view of U.S. Patent No. 6,258,046 to Kimball (Kimball). These claims have been amended to include the limitation that the CO₂ detecting machine is for detecting and determining the amount of ambient or respired CO₂. Support for this limitation can be found at page 4, lines 31-36 which define what is meant by CO₂ detecting machine. The definition refers to capnographs and capnometers which are used to detect ambient and respired CO₂ levels and not devices attached to laser-Doppler sensors (as in Kimball). It is further noted at page 5, lines 8-14 that the present invention can detect both substantial amounts of CO₂ as well as little or no CO₂. The fact that

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Kimball is not concerned with ambient or respiration CO_2 is confirmed at column 3, lines 60-64 which disclose that ambient CO_2 levels will not interfere in the tissue perfusion assessment, meaning that ambient CO_2 amounts are not measured, otherwise they would interfere with the assessment. Such levels are exactly the type of CO_2 levels that a CO_2 detector that detects ambient and respiration amounts of CO_2 will measure. If the concentration of CO_2 measured by a CO_2 detector is too high, as determined by the readout on the machine, a person using the present invention will know that the tube is being improperly placed in the trachea. Accordingly, Kimball actually teaches away from a CO_2 detector as required by the claims. Such a machine is not disclosed or suggested by Kimball as none of the devices described by Kimball function (or could function) as a CO_2 detecting machine that detects and determines the amounts of ambient and respiration CO_2 . Furthermore, there is no teaching or suggestion to combine Piontek and Kimball as the two devices have different functions altogether. Piontek is a surgically placed feeding tube while Kimball detects tissue perfusion. Of course, the teaching or suggestion to combine the references must come from the prior art and not applicant's disclosure and the references cannot be modified in a way that destroys their intended function. In this situation, if the device 30 of Kimball were a CO_2 detector that detects and determines the amounts of ambient and respiration CO_2 , the function of Kimball would be destroyed because Kimball does not want to measure such CO_2 amounts. Moreover, obvious to try is not the standard for obviousness. Accordingly, the combination of Piontek and Kimball cannot be said to obviate the present invention and applicants respectfully request that this rejection be withdrawn.

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Applicants also note a reference to Babb et al. (U.S. Patent No. 5,197,464) which discloses an invention which ascertains whether there is at least a threshold concentration of CO₂ in a monitored gas. Babb does not suggest or disclose a CO₂ detector which detects and determines the amount of ambient or respired CO₂, rather, Babb, utilizes CO₂ detectors which employ a color-changing indicator solution which changes color only if a threshold level of CO₂ is present (see column 6, lines 38-41; column 6, lines 58-64; column 7, lines 14-32; and column 7, line 57- column 8, line 3). Thus, the only knowledge gained is whether or not the threshold has been reached and not the *amount* of CO₂. The potential problem of measuring CO₂ in the esophagus is discussed and it is noted for each embodiment discussed that false readings may initially occur, however, the color indicator should eventually return to a color indicating that the threshold level of CO₂ and that the tube is improperly placed in the esophagus. This of course is the reverse of the present invention which must need to know if the tube is properly placed in the esophagus and not in the respiratory tract. Thus, the method and apparatus of Babb does not disclose or suggest the presently claimed invention which comprises a feeding tube and a CO₂ detecting machine which measures the amount of CO₂ and does not merely indicate whether a threshold amount of CO₂ is present. Accordingly, there is no prior art of record of a feeding tube which teaches or suggests combining the feeding tube with a CO₂ detector which detects amounts of ambient and respired CO₂, nor is there any prior art of record of such a CO₂ detector combined with a feeding tube. The only such disclosure or suggestion is in applicant's specification.

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New claim 16 is a combination of former claims 12 and 11 which was indicated as allowable in the last office action if the claim was rewritten in independent format and including all limitations of the two claims. Accordingly, Applicant asserts that this claim is allowable.

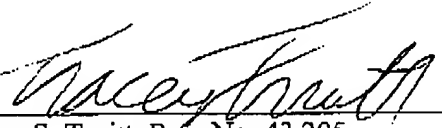
Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached pages are captioned "Version with marking to show changes made."

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Respectfully submitted,

By


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"Version with markings to show changes made."

Claims:

Please cancel claims 4, 5, 11, 12, and 15 without prejudice.

Please add new claim 16.

Please amend the following claim:

7. (Amended) A feeding tube and CO₂ detecting machine combination comprising:
an elongated patient feeding tube presenting a distal end adapted for insertion into a
patient and a proximal portion designed to remain outside the patient; and
a CO₂ detecting machine operably coupled with said proximal portion of said tube so that
the presence of CO₂ adjacent said distal end may be detected when the tube is
inserted into a patient, said CO₂ detecting machine for detecting and determining
the amount of ambient or respiration CO₂.

Please add the following new claim:

16. A fixture for connection to the proximal end of a feeding tube, said fixture
comprising a bifurcated body presenting first and second tubular legs, said first leg having a
connection end adapted for attachment to said proximal end to form a continuation thereof, said
second leg in communication with the first leg and including at least one intermediate coupling
member adapted for connection with a CO₂ detecting machine, said fixture further including a

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guide wire extending through said first leg and feeding tube, there being a guide wire mount removably secured to an end of said first leg remote from said connection end.